

REMARKS

Favorable reconsideration, reexamination, and allowance of the present patent application are respectfully requested in view of the foregoing amendments and the following remarks. The foregoing amendments are fully supported by the original specification and claims, and at least on page 19, lines 2-25, page 23, lines 8-9, and page 24, lines 8-10. No new matter has been added.

Amendments

Claims 2 and 31 are canceled. Claims 4-30 are withdrawn. Claims 1, 3, 32, and 33 are amended.

Objection to the Specification

At page 2 of the Office Action, the Specification was objected to because it allegedly contains a hyperlink. Applicants respectfully request reconsideration of this objection.

The specification has been amended to delete the hyperlink.

For at least the foregoing reasons, Applicants respectfully submit that the Specification is not objectionable, and therefore respectfully request withdrawal of the objection thereto.

Objection to the Claims

At page 2 of the Office Action, Claim 1 was objected to because it allegedly contained a typographical error. Applicants respectfully request reconsideration of this objection.

Claim 1 has been amended to remove the typographical error.

For at least the foregoing reasons, Applicants respectfully submit that Claim 1 is not objectionable, and therefore respectfully requests withdrawal of the objection thereto.

Rejection under 35 U.S.C. § 112, first paragraph, enablement

In the Office Action, beginning at page 2, Claims 1-3, 31 and 33 were rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matters that allegedly failing to

comply with the scope of enablement requirement. Applicants respectfully request reconsideration of this rejection.

The Office Action states on page 3 a variation of 1-12 amino acids in SEQ ID Nos. 4 and 6 “is not a small variation”. Claim 31, however, is limited to a variation of 1 to 5 amino acids, and this claim, although included in the Examiner’s rejection, was not separately addressed. As the scope of claim 31 was not separately addressed, particularly when the basis for the rejection lies in the “1 to 12” limitation, and claim 31 further limits the claims to “1 to 5”, consideration of this limitation is respectfully requested, even if the finality of the rejection must be withdrawn. 35 U.S.C. §132(a) requires that when any claim is rejected, the reasons for the rejection must be stated. The reasons for the rejection of “1 to 5 amino acids” was never stated in the Office Action. Furthermore, 37 C.F.R. §1.104(b) requires that the examiner's action will be complete as to all matters. It is asserted that the Examiner’s action was incomplete as the limitation of claim 31 was not addressed or even acknowledged, and the reasons for the rejection only address the limitation of “1 to 12”, and not the claim 31 limitation of “1 to 5”. Withdrawal of the finality and examination of this claims is respectfully requested.

Regardless, Applicants have amended claim 1 to recite that the variation in the amino acid sequence is 1 to 5. This is a very small variation and well within the skilled art worker’s expertise to determine variant proteins which will maintain the required function. The argument set forth on page 5 of the Office Action concerning post-translational modification is not entirely applicable to the claims, as the claims are directed to a bacterium. It is well-known in the art that bacteria constitute a much simpler system, and most do not typically undergo many post-translational modifications, so the arguments in the Office Action are not entirely applicable. Furthermore, the examples cited of one amino acid having a large effect on the activity of a protein are all in higher organisms, not in the claimed bacteria. Bacteria have much simpler systems, and therefore, the experimentation required to determine protein activity is concomitantly lower.

Also, the argument on page 3 of the Office Action regarding the pure mathematical number of variants also does not apply. The skilled art worker would not have to make every variant to determine activity, but would be able to use their skill and

knowledge that conservative substitutions increase the chance for retention of activity, whereas non-conservative substitutions do not. Such experimentation is clearly routine and not undue.

The assertion that the claims encompass only a sequence of two amino acids set forth on page 4 of the Office Action has been addressed by changing the article “an amino acid” to “the amino acid”. Clearly, this renders the claims clear and definite as to the scope, and clearly requires that the amino acid sequence be that of the entire SEQ ID No. 4, or stated variants within 1-5 amino acids.

Regarding the assertion that Applicant has not provided a means for increasing the activity of the claimed proteins, the claims have been amended to state that the expression of the protein is increased. Specifically the expression is increased by transforming the bacterium with the gene encoding said protein, or placing the gene under the control of a potent promoter, which method are stated in the claims.

For at least the foregoing reasons, Applicants respectfully submit that Claims 1-3, 31 and 33 fully comply with 35 U.S.C. § 112, first paragraph, and therefore respectfully request withdrawal of the rejection thereof under 35 U.S.C. § 112.

Rejection under 35 U.S.C. § 112, first paragraph, new matter

In the Office Action, beginning at page 9, Claims 1-3 and 31-33 were rejected under 35 U.S.C. § 112, first paragraph, as reciting subject matters that allegedly failing to comply with the written description requirement for new matter. Applicants respectfully request reconsideration of this rejection.

The Office Action states that the range of “1 to 12” or “1 to 11” are not supported by the specification. The claims have been amended to replace these ranges with “1 to 5”. All of these ranges are fully supported by the specification. Specifically, the original claim term was “one or several” amino acids. The term “several” is clearly defined on page 15, lines 5-11 of the specification. One possibly definition for this term is “2 to 5”. Since the original expression was “one or several”, and taking the definition of “several” as “2 to 5”, there is clearly support for “one, or 2 to 5”. This expression is clearly equivalent to “one to 5” and “1 to 5”. Therefore, the expression of “1 to 5 amino acids” is adequately and clearly supported by the specification and the original claims.

For at least the foregoing reasons, Applicants respectfully submit that Claims 1-3 and 31-33 fully comply with 35 U.S.C. § 112, first paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

Rejection under 35 U.S.C. § 112, second paragraph

In the Office Action, beginning at page 10, Claims 1-3 and 31-33 were rejected under 35 U.S.C. § 112, second paragraph, as reciting subject matters that allegedly are indefinite. Applicant respectfully requests reconsideration of this rejection.

The phrase “increasing the activities of a protein” was rejected as being vague and indefinite. This phrase has been amended to specify that the expression of the protein is being increased by a particular method.

The phrase “or its analogs to the bacterium” was rejected as being vague and indefinite. Claim 1 is amended to state “amino acid and/or analogs thereof”.

Claim 2 is rejected as being indefinite on the grounds that there is insufficient antecedent basis for “said DNA”. Claim 2 has been canceled without prejudice.

Claim 31 is rejected as being indefinite due to the phrase “wherein the number of deletion, substitution, insertion or addition of amino acids in the amino acid sequences in SEQ ID NOs: 4 and 6 is 1-5.” Claim 31 has been canceled without prejudice.

Claim 32 is rejected as being indefinite on the grounds that it depends from claim 31, and claim 33 is rejected as being indefinite on the grounds that this claim depends from claim 32. Claim 32 has been amended to depend from claim 1.

For at least the foregoing reasons, Applicants respectfully submit that Claims 1-3, 31, and 33 fully comply with 35 U.S.C. § 112, second paragraph, and therefore respectfully requests withdrawal of the rejection thereof under 35 U.S.C. § 112.

Rejection under 35 U.S.C. § 102

In the Office Action, beginning at page 6, Claims 1-2 and 31-33 were rejected under 35 U.S.C. § 102(b), as reciting subject matters that allegedly are anticipated by Furukawa et al.. Applicants respectfully request reconsideration of this rejection.

Furukawa et al. clearly fails to teach either the presence of the protein of SEQ ID NO. 4 or SEQ ID NO. 6, let alone the enhanced expression of either of these proteins, or

the enhanced expression of both proteins, as required by the claims. Furthermore, Furukawa et al. fail to show that the combined increased activity of these proteins will result in increased L-amino acid production. Therefore, the Office Action fails to show each and every limitation of the claims is present in the single prior art reference, and furthermore, the Office Action fails to provide any evidence of the inherency of these limitations.

The assertion in the Office Action that the claims are written as product-by-process claims is entirely incorrect, however to advance prosecution, the claims have been amended to clarify the structural characteristics of the claimed bacterium. The claims are directed to a bacteria, and the structural characteristics of the claimed bacteria are defined by an increase in expression of particular defined proteins. The bacterial product is not claimed by a process of making, as there are no process steps in the claim. The bacterial product is defined by having increased expression of certain defined proteins. Clearly, the cited art fails to teach or suggest such increased expression in a bacterial product, as the claimed proteins are not taught by the art.

For at least the foregoing reasons, Applicants respectfully submit that the subject matters of Claims 1-2 and 31-33 are not anticipated by Furukawa et al., are therefore not unpatentable under 35 U.S.C. § 102(b), and therefore respectfully request withdrawal of the rejection thereof under 35 U.S.C. § 102(b).

In the Office Action, beginning at page 8, Claims 1-3 and 31-33 were rejected under 35 U.S.C. § 102(b), as reciting subject matters that allegedly are anticipated by Sano et al.. Applicants respectfully request reconsideration of this rejection.

Similar to Furukawa et al., Sano also clearly fails to teach either the presence of the protein of SEQ ID NO. 4 or SEQ ID NO. 6, let alone the enhanced expression of either of these proteins, or the enhanced expression of both proteins, as required by the claims. Furthermore, Sano fail to show that the combined enhanced expression of these proteins will result in enhanced L-amino acid production. Therefore, the Office Action fails to show each and every limitation of the claims is present in the single prior art reference, and furthermore, the Office Action fails to provide any evidence of the inherency of these limitations.

Similar to the argument above, the assertion in the Office Action that the claims are written as product-by-process claims is entirely incorrect, however to advance prosecution, the claims have been amended to clarify the structural characteristics of the claimed bacterium. The claims are directed to a bacteria, and the structural characteristics of the claimed bacteria are defined by an increase in expression of particular defined proteins. The bacterial product is not claimed by a process of making, as there are no process steps in the claim. The bacterial product is defined by having increased expression of certain defined proteins. Clearly, the cited art fails to teach or suggest such increased expression in a bacterial product, as the claimed proteins are not taught by the art.

For at least the foregoing reasons, Applicants respectfully submit that the subject matters of Claims 1-3 and 31-33 are not anticipated by Sano et al., are therefore not unpatentable under 35 U.S.C. § 102(b), and therefore respectfully request withdrawal of the rejection thereof under 35 U.S.C. § 102(b).


Conclusion

For at least the foregoing reasons, Applicants respectfully submit that the present patent application is in condition for allowance. An early indication of the allowability of the present patent application is therefore respectfully solicited.

If Examiner Gangle believes that a telephone conference with the undersigned would expedite passage of the present patent application to issue, he is invited to call on the number below.

It is not believed that extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to our Deposit Account 50-2821.

Respectfully submitted,

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